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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,784	03/09/2001	Frederick J. Cassels		1381

7590

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/801,784

Applicant(s)

Cassels et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 14, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 3, 8, and 9 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 4-7 ~~is/are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 04/14/03 (paper no. 15) in response to the non-final Office Action mailed 01/08/03 (paper no. 14). With this, Applicants have substituted the specification.

### **Status of Claims**

- 2) Claims 1, 2 and 5-7 have been amended via the preliminary amendment filed 04/14/03.  
Claims 1-9 are pending.  
Claims 1, 2 and claims 5-7 are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 5) The objection to the specification made in paragraph 6(a) of the Office Action mailed 04/14/03 (paper no. 15) is withdrawn in light of Applicants' amendment to the specification.
- 6) The objection to the specification made in paragraph 6(b) of the Office Action mailed 04/14/03 (paper no. 15) is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 6(d) of the Office Action mailed 04/14/03 (paper no. 15) is withdrawn in light of Applicants' amendment to the specification.
- 8) The objection to the specification made in paragraph 6(e) of the Office Action mailed 04/14/03 (paper no. 15) is withdrawn in light of Applicants' amendment to the specification.
- 9) The objection to the specification made in paragraph 6(f) of the Office Action mailed 04/14/03 (paper no. 15) is withdrawn in light of Applicants' amendment to the specification.

### **Objection(s) Maintained**

- 10) The objection to the specification made in paragraph 6(c) of the Office Action mailed

Serial Number: 09/801,784  
Art Unit: 1645

04/14/03 (paper no. 15) is maintained for reasons set forth therein. The three amino acid sequences recited on page 6: VEKNITVTASVDPTIDLLQADGSALPSAVALTYSPA, are longer than four amino acids and in length, yet are not identified by a sequence identifier, i.e., SEQ ID number as required under 37 C.F.R. 1.821-1.825. The objection stands.

#### **Rejection(s) Withdrawn**

**11)** The rejection of claim 1 made in paragraph 7 of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

**12)** The rejection of claims 1, 2 and 5-7 made in paragraph 9 of the Office Action mailed 04/14/03 (paper no. 15) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6-11 of the US patent 5,914,114 (Cassels) ('114), is withdrawn upon further consideration and in light of Applicants' arguments.

**13)** The rejection of claim 2 made in paragraph 10(a) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**14)** The rejection of claim 1 made in paragraph 10(b) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**15)** The rejection of claim 1 made in paragraph 10(c) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**16)** The rejection of claim 7 made in paragraph 10(d) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**17)** The rejection of claim 5 made in paragraph 10(e) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**18)** The rejection of claims 5-7 made in paragraph 10(f) of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of

Serial Number: 09/801,784  
Art Unit: 1645

Applicants' amendment to the base claim(s).

19) The rejection of claims 1, 2 and 5-7 made in paragraph 12 of the Office Action mailed 04/14/03 (paper no. 15) under 35 U.S.C. § 103(a) as being unpatentable over Cassels (US 5,914,114) (Cassels, '114) or Cassels (WO 96/38171) ('171), is withdrawn upon further consideration and in light of Applicants' arguments.

#### **New Rejection(s)**

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims.

#### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

20) Claims 2 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 2 is vague and indefinite in the recitation "at least one peptide of claim 1", because claim 1 is drawn to 'An isolated peptide', not to more than one isolated peptide. The term 'at least one' encompasses more than one, and claim 1 does not claim more than one isolated peptide.

(b) Claims 5-7, which depend directly or indirectly from claim 2, are also rejected as being indefinite, because of the indefiniteness identified above in the base claim.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

21) Claims 1, 2 and 5-7 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended, now includes the new limitation: "selected for a consecutive sequence". However, the instant application does not appear to have descriptive support for these new limitations. Applicants have not pointed to a specific part of the specification that provides descriptive support for the new limitation identified above. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific

Serial Number: 09/801,784  
Art Unit: 1645

percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the specification where support for such a recitation can be found.

### Remarks

22) Claims 1, 2 and 5-7 stand rejected.

To obviate the rejections of record, it is suggested that Applicants amend claim 1 to read:

--Claim 1. An isolated 16 to 30 amino acid-long peptide obtained from the peptide of the amino acid sequence, VEKNITVTASVDPTIDLLQADGSALPSAVALTYSPA (SEQ ID NO. 1), said isolated peptide containing the amino acid sequence PSAVALTYSP (SEQ ID NO: 36).--

It is further suggested that Applicants amend claim 2 to read:

--Claim 2. A composition comprising the isolated peptide of claim 1 in a pharmaceutically acceptable carrier.--

Claim 5 depends indirectly from the base claim 1. Claim 1 recites two peptides: (a) an isolated 16-30 amino acid-long peptide, and (b) a longer peptide from which the 16-30 amino acid-long peptide is obtained from. In claim 5, for proper antecedence and clarity, it is suggested that the term "the peptide" is replaced with --the isolated peptide-- since isolated is the one which is bound to bovine serum albumin.

23) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

24) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Serial Number: 09/801,784  
Art Unit: 1645

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

June, 2003

  
S. DEVI, PH.D  
PRIMARY EXAMINER